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10/618,033	07/11/2003	Yaron Keidar	50572/AW/W112	4112
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CHRISTIE, PARKER & HALE, LLP			EXAMINER	
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PASADENA, CA 91109-7068				
			ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/618,033

Applicant(s)

KEIDAR, YARON

Examiner

Timothy J. Neal

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 April 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 20-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This action is in response to the correspondence received on 4/26/2007. The Applicant has sworn behind the Kerr reference from the prior final action requiring the Examiner to provide a new rejection with new art. This action is considered final because of the amendments to the claims submitted 11/15/2006.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Bonutti (US 5,814,073).

Bonutti discloses:

1. A device comprising: an elongated tubular body having an axis, a proximal end, a distal end and a lumen longitudinally extending therethrough (54); and a dilating tip slidably mounted on the distal end of the tubular body (30) and comprising a segmented surface (Items 88, 90, 92, and 94) that is generally transverse to the axis of the tubular body, and a generally rigid tube extending distally from the segmented surface and having a sharp distal end adapted to puncture tissue (Column 3 Lines 56-67); wherein

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distal movement of the tubular body relative to the dilating tip exerts a force on the segmented surface to thereby open the segmented surface (Figs 1 and 2).

2. A device according to claim 1, wherein the elongated tube is generally cylindrical (54).

3. A device according to claim 1, where the segmented surface comprises two or more segments (88, 90, 92, and 94).

4. A device according to claim 1, where the segmented surface comprises three or more segments (88, 90, 92, and 94).

5. A device according to claim 1, wherein the dilating tip further comprises a ring mounted in surrounding relation to the tubular body (Fig 1).

6. A device according to claim 5, wherein the segmented surface comprises a plurality of segments, each of which is hingedly attached to the ring (Fig 2).

7. A device according to claim 1, wherein the dilating tip is generally funnel-shaped (Fig 1).

8. A device according to claim 1, wherein the generally rigid tube of the dilating tip is

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segmented (Fig 1).

18. A device comprising: an elongated tubular body having an axis, a proximal end, a distal end and a lumen longitudinally extending therethrough (54); a dilating tip slidably mounted on the distal end of the tubular body (30) and comprising: a ring mounted in surrounding relation to the distal end of the tubular body (proximal portion of Item 30); a segmented surface that is generally transverse to the axis of the tubular body, the segmented surface comprising three or more segments (88, 90, 92, and 94), each segment being hingedly attached to the ring (Fig 2); and a generally rigid tube extending distally from the segmented surface (Fig 1), the tube having a sharp distal end adapted to puncture tissue (Column 3 Lines 56-67) and being segmented into three or more segments (88, 90, 92, and 94); wherein distal movement of the tubular body relative to the dilating tip exerts a force on the segmented surface and the generally rigid tube to thereby open the segmented surface and the generally rigid tube (Figs 1 and 2).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 9-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bonnuti '073.

Bonnuti discloses the invention substantially as claimed as stated above.

Bonnuti does not explicitly disclose the claimed lengths and diameters of the generally rigid tube of the dilating tip. However, the Examiner considers it within the purview of one having ordinary skill in the art to modify a device's length and diameter to meet the desired sizes for a given application. Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Bonnuti's dimensions to include those of the claims. Such a modification would be necessary for the device to be used in certain applications.

Bonnuti also does not explicitly disclose the use of nitinol for the tip. However, the Examiner considers it to be old and well known in the art to use nitinol in a variety of applications because it is biocompatible. Bonnuti discloses the use of biologically compatible alloys for use with his invention (Paragraph 15). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Bonnuti's tip to include nitinol. Such a modification would provide a well-known alloy with desirable biocompatibility.

Claims 14-16 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bonnuti '073 in view of Wallace et al. (US 6,254,628).

Bonnuti discloses the invention substantially as claimed as stated above.

Bonnuti does not explicitly disclose a wire extending proximally from the dilating tip to near the proximal end of the tubular body to effect proximal movement of the dilating tip relative to the tubular body and a slidable member on the proximal end of the tubular

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body, the slidable member being connected to the wire so that proximal movement of the slidable member pulls the wire and causes the proximal movement of the dilating tip relative to the tubular body. Wallace teaches the concept of controlling the distal movement of a retractable or sliding element from the proximal end of the device (Fig 28-34). Wallace teaches a pull tab connected to a pull wire that is connected to a pulling control mechanism on the proximal end of the catheter (Col 18 Line 66 through Col 19 Line 3). Therefore, it would have been obvious to a person having ordinary skill in the art to modify Bonnuti's device to include Wallace's pull wire and proximal member. Such a modification would allow the operator to manipulate the action of the distal tip from a location proximal to the tip, possibly outside the body.

Bonnuti and Wallace disclose the invention substantially as claimed. They do not disclose a latch for maintaining the position of the slidable member. However, the Examiner considers latches to be known for selectively maintaining the position of a wide variety of elements. Therefore, it would have been obvious to a person having ordinary skill in the art to modify Bonnuti and Wallace's device to include a latch mechanism for maintaining the position of the slidable member. Such a modification would prevent the tip from undesirably opening. It gives the operator control over the opening and closing of the distal tip. If the tip opens prematurely, damage will occur to the surrounding tissue.

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bonnuti '073 in view of Devos et al. (US 6,099,511).

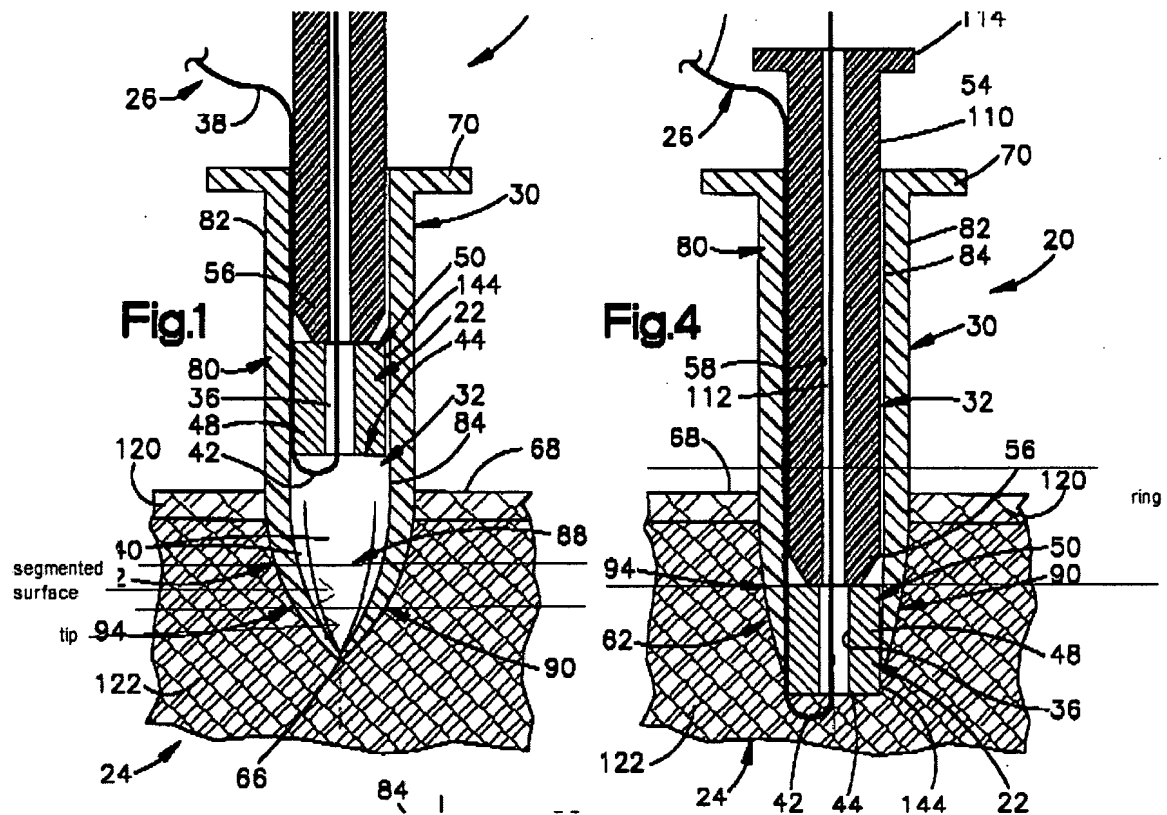
Bonnuti discloses the invention substantially as claimed as stated above.

Bonnuti does not disclose a pressure valve at or near the proximal end of the tubular body. Devos teaches a pressure valve at or near the proximal end of the tubular body (Fig. 1 Item 30). Therefore it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Bonnuti's apparatus to include Devos's pressure valve. Such a modification would be to measure different pressures in a catheterized heart.

Response to Arguments

Applicant's arguments with respect to claims 1-19 have been considered but are moot in view of the new ground(s) of rejection.

The Applicant has sworn behind the Kerr reference of the previous final rejection. The Examiner has provided a new reference with an earlier date. The Bonnuti reference is very similar to the Kerr reference. Because of the similarity, the Examiner will refer the Applicant to the previous action for a more complete response to arguments and explanation of the prior art. The marked-up drawings of the Kerr reference detail the interpretation of the prior art and may be applied to the Bonnuti reference (figures 1 and 2 of Bonnuti are similar to figures 9 and 10 of Kerr). Below is a marked up drawing from Bonnuti showing the segmented surface, the tip, and the ring. Because no further arguments were made, the Examiner considers this response sufficient.



Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Timothy J. Neal whose telephone number is (571) 272-0625. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TJN


ANHTUAN T. NGUYEN
SUPERVISORY PATENT EXAMINER

5/14/07.